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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,160	03/01/2007	Mary Ellen Rybak	13566.105023	1564
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KING & SPALDING 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036-4003			EXAMINER LEWIS, PATRICK T	
			ART UNIT 1623	PAPER NUMBER
			NOTIFICATION DATE 11/02/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary

Application No.

10/579,160

Applicant(s)

RYBAK, MARY ELLEN

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 21 is/are rejected.
- 7) ☒ Claim(s) 17-20 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 05112006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claim Objections

1. Claims 17-20 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 17-20 have not been further treated on the merits.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bowman et al. WO 00/69441 (Bowman).

Bowman teaches treating any mammal affected by cancer comprising administering a therapeutically effective amount of ET-743, or a pharmaceutical composition thereof (pages 7-8). Administration of the compounds is preferably by intravenous infusion. Infusion times of up to 72 hours are used. The correct dosage of the compound will vary according to the particular formulation, mode of application, and the particular *situs*, host and tumor being treated. Administration can be carried out continuously or periodically within the maximum tolerated dose. ET-743 may be used

with other drugs to provide a combination therapy. The other drugs may form part of the same composition, or be provided as a separate composition for administration at the same time or a different time. Suitable candidates include antimetabolite drugs such as 5-fluorouracil.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowman et al. WO 00/69441 (Bowman) as applied to claim 1 above, and further in view of Ishikawa et al. Biochemical Pharmacology (1998), Vol. 55, pages 1091-1097 (Ishikawa).

Claims 1-16 are drawn to a method of treating a human body having cancer comprising administering an effective therapeutic amount of ET-743 in combination with

an effective therapeutic amount of 5-fluorouracil or a pro-drug thereof. Claim 21 is drawn to a medical kit for administering ET-743 in combination with capecitabine.

Bowman teaches treating any mammal affected by cancer comprising administering a therapeutically effective amount of ET-743, or a pharmaceutical composition thereof (pages 7-8). Administration of the compounds is preferably by intravenous infusion. Infusion times of up to 72 hours are used. The correct dosage of the compound will vary according to the particular formulation, mode of application, and the particular *situs*, host and tumor being treated. Administration can be carried out continuously or periodically within the maximum tolerated dose. ET-743 may be used with other drugs to provide a combination therapy. The other drugs may form part of the same composition, or be provided as a separate composition for administration at the same time or a different time. Suitable candidates include antimetabolite drugs such as 5-fluorouracil.

Bowman differs from the instantly claimed invention in that Bowman does not teach the administration of capecitabine or other 5-fluorouracil pro-drugs; however, the use of capecitabine would have been obvious to one of ordinary skill in the art at the time of the invention.

Ishikawa teaches that cytotoxic anticancer drugs often cause severe side-effects because they do not act selectively in tumors. Capecitabine was designed to generate the active drug 5-FUra selectively in human tumors through three sequential steps of enzyme reactions in humans. Because these enzymes are so localized in the body,

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capecitabine is expected to generate 5-FUra selectively in tumor tissues, and consequently, to improve the efficacy and safety margins of 5-FUra, the parent drug.

It would have been obvious to one of ordinary skill in the art to use capecitabine. As taught by Ishikawa, capecitabine generates the active drug 5-FUra selectively and consequently, improves the efficacy and safety margins of the parent drug. Selection of appropriate dosage regimens will vary according to the particular formulation, mode of application, and the particular *situs*, host and tumor being treated, and such selection would have been well within the purview of the skilled artisan.

Conclusion

7. Claims 1-21 are pending. Claims 1-16 and 21 are rejected. Claims 17-20 are objected to. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Dr. Patrick T. Lewis
Primary Examiner
Art Unit 1623

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